amount of rFVIIa used to achieve haemostasis. A Generalized Linear Regression Model was used to derive the potential cost-offsets of a novel treatment. The net monetary benefit per bleeding treated of the novel treatment compared to rFVIIa was estimated using a variety of assumptions on the efficacy of the novel treatment as well as on the valuation of the health benefits. **RESULTS:** Assuming a reduction in time to bleeding resolution by 25%, a novel treatment saved €339 per bleeding compared to rFVIIa. Including the value of the health benefits, which were estimated to €51, the net monetary benefit of the novel treatment was €390 per bleeding. The results were sensitive to assumptions around the efficacy of the new treatment but also around the valuation of health benefits. **CONCLUSIONS:** A novel treatment which reduces time to bleeding resolution would entail important health economic benefits, both in terms of health care cost-offsets and health benefits. One limitation of cost-effectiveness analyses in hemophilia is the uncertainty around the valuation of short term health benefits.

PIH43

METHODOLOGY TO IDENTIFY IN-VITRO FERTILIZATION PATIENTS USING A NATIONAL MANAGED CARE DATABASE

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BACKGROUND: The majority of analyses of outcomes related to fertility treatments are conducted in datasets from fertility centers. To date there has been no established methodology for identifying fertility protocols in payer databases. **OBJECTIVES:** To identify a methodology for identifying fertility protocols in a national administrative claims database. **METHODS:** This retrospective descriptive study used PharmMetrics, a national managed care dataset. Patients with at least one prescription for a gonadotropin-releasing hormone agonist (GnRHAg) or antagonist (GnRHAnt) between January 1, 1999 and May 31, 2009 were selected. Drugs billed with a National Drug Code were included and were identified using generic product identifiers. Index date was set as the first pharmacy claim date for a GnRHAg or GnRHAnt. Patients were excluded if no prescription record for FSH existed in the 7 days pre-index through 60 days post-index and HCG in the 60 day post-index period. Patients must be eligible for services for 12 months before and after the index date, which established continuous eligibility for services. Longer eligibility allows assessment of outcomes such as birth rates. The final sample consisted of patients with an embryo transfer code within 60 days of index. Outcome of delivery codes served as indicators for live birth if they occurred within 294 days (42 weeks) after transfer date. **RESULTS:** Inclusion and exclusion criteria were applied to patients that had at least one prescription for GnRHAnt or GnRHAg, resulting in some attrition of sample (880 patients with IVF). The 2-year continuous eligibility requirement accounted for the largest number of patients removed. **CONCLUSIONS:** Administrative claims data provide a large sample of IVF patients, but are limited in some analyses due to a lack clinical details. The proposed methodology was able to successfully identify IVF treatment cycles and link these to delivery outcomes for treated patients under real-world conditions.

PIH44

MULTIDOMAIN LONGITUDINAL MODELING: APPLICATION TO THE INTERNATIONAL INDEX OF ERECTILE FUNCTION

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OBJECTIVES: Individual domains of multidomain patient-reported outcome instruments typically are analyzed independently, without considering inherent dependency of component domains. This report presents an underused modeling approach that accounts for correlations across time (longitudinal) and correlations across domains of a multidomain instrument in one integrated model. **METHODS:** International Index of Erectile Function (IIEF) data from a double-blind placebo-controlled trial of fixed-dose sildenafil (50 or 100 mg) in 288 men with erectile dysfunction were used. Standard methodology was used for the individual-domain longitudinal model. This model was then expanded to account for relationships among domains for the multidomain longitudinal model, performing modeling of treatment effects on all domains simultaneously. Covariance was constructed by taking the Kronecker product of an unstructured covariance matrix across domains (modeling covariance across the domains) with an unstructured covariance matrix across time (modeling covariance across time). Analyses were performed with Proc Mixed using SAS v9.2. **RESULTS:** The model was constructed and fitted, which integrated all IIEF domains simulataneously into one unified multidomain longitudinal model. Treatment effects for all 5 IIEF domain scores calculated using individual or multidomain modeling were similar, reflecting the robust application of IIEF data in this study. **CONCLUSIONS:** Modeling correlation structure simultaneously across domains of a multidomain instrument, as well as across time, more rigorously addresses the interrelationship between domains and potentially presents a more accurate estimation of efficacy and statistical inferences. Additional work with simulations and more empirical evidence are needed to better understand the multidomain longitudinal model.

PIH45

MULTILEVEL ANALYSIS TO MEASURE HOSPITAL VARIATION: THE CASE OF CESAREAN DELIVERY

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OBJECTIVES: Efficiency in health systems is often a matter of concern and differences on the expected productivity of a given procedure might lead to inefficient variations in the performance of such interventions. Health economics literature has extensively revisited the topic of variations in health care using multivariate models to predict variation across geographic regions. The clustering effect of facilities (as a functional unit), however. has not been described before. This analysis examines the extent to which facilities explain geographic variation in health care. **METHODS:** A set of individual data on all births from a Contributory-Regimen insurer in Colombia was assessed. We performed a multilevel logistic regression model, taking hospitals as the clustering variable. In addition, we included an alternative variance decomposition specification to estimate the attributable effect of geographic region on the variability across hospitals. We used a set of variables including mother education and income, physician fees, and complications during pregnancy to control for in this analysis. **RESULTS:** Our results reveal that hospitals account for 20% of variation on the probability of performing cesarean sections. Geographic area only explains one-third of the variance attributable to the hospital. In addition, physician fees (0.077; SE 0.023), mother's income (0.070; SE 0.014) and superior education in mothers (0.299; SE 0.107). This supports the effect of mother and physician preferences on variations. **CONCLUSIONS:** This paper contributes to previous research by using a multilevel model approach and by defining hospitals as cluster. We found a strong effect of hospitals on determining variations. In addition, we found how supply-side factors such as physician fees and demand-side factors (proxies for preferences) such as mother's education and income are affecting variations across hospitals and regions. The effect of facility as well as individual-level variables should be taken into account when researching on variations in health care.

PIH46

SPECIAL PRECAUTIONS TO CONSIDER WHEN PERFORMING COGNITIVE DEBRIEFING OF SENSITIVE TOPICS

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OBJECTIVES: The linguistic validation and cognitive debriefing of PROs are now well documented and routinely used within the pharmaceutical industry to ensure that the translated instruments are conceptually equivalent to their sources. Increasingly, new adjustments are being developed to further customize these processes according to the special needs of the instrument and target culture. This paper seeks to enumerate the challenges faced when debriefing questionnaires of an embarrassing, and potentially offensive, nature and recommends the use of a specialized methodology to make respondents more comfortable during this process. **METHODS:** To establish guidelines for debriefing PROs of a sensitive nature, subject feedback from previous ED questionnaire debriefing reports was examined. The subjects that expressed the most discomfort during the debriefing process resided in India, Africa, and the Middle East. Additionally, older subjects and subjects with lower levels of education were more likely to express reservations. For this study, we collaborated with translators from each of these regions to determine a list of measures that can be taken to help ensure that subjects feel comfortable enough to provide reliable feedback within the interview setting. **RESULTS:** The goal of any cognitive debriefing session is to adequately test the translated questionnaire while maintaining the cultural sensitivities of the target country. Recommended considerations include: assigning an interviewer of the same sex as the subject, performing a specialized training session with interviewers that reviews subjects' boundaries and strategies for effective probing, sending subjects an introductory note that emphasizes confidentiality prior to the interview, conducting interviews via telephone rather than in-person, and debriefing questionnaires via a web-based device. **CONCLUSIONS:** For some cultures, cognitively debriefing PRO questionnaires of a sensitive nature places added burden on respondents. Evidence suggests that additional considerations should be exercised during debriefing to respect subjects' cultural boundaries.

Infection – Clinical Outcomes Studies

PIN1

VACCINE-ASSOCIATED GUILLAIN-BARRE SYNDROME: A PHARMACOVIGILANCE ANALYSIS OF DATA IN THE UNITED STATES' VACCINE ADVERSE EVENT REPORTING SYSTEM (1990-2009)

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OBJECTIVES: To describe reporting rates and characteristics of vaccine-associated GBS reports in the Vaccine Adverse Event Reporting System (VAERS) over a two-decade period. **METHODS:** Adverse event reports submitted to VAERS from January 1990 to November 2009 are utilized to conduct a retrospective pharmacovigilance analysis by calculating the proportional reporting ratios (PRR) and corresponding 95% confidence intervals (CI) for vaccine-GBS event pairs. **RESULTS:** One thousand and 259 reports of vaccine-associated GBS are identified for 37 vaccines. The mean age of patients experienced GBS after vaccination was 31 years; 51% of patients were females. Majority of the reports were for influenza (FLU) (791) and hepatitis B (HEP) virus vaccines (103). Reports for human papillomavirus quadrivalent (HPV4), meningococcal conjugate (MNQ), and measles/mumps/rubella (MMR) virus vaccines accounted for 37, 36, and 34 reports, respectively. Death, disability and hospitalization among the serious GBS outcomes were correspondingly reported in 36 (2.9%), 199 (15.8%), and 963 (76.4%) reports. Most of these outcomes were in FLU reports. The average postvaccination GBS onset delay was 3.5 weeks; ranging from 2.3 weeks for FLU to 8.1 weeks for MNQ. About 79% and 12% of GBS reports included